



UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/544,984 04/07/00 KLEIN

P 44033-093

WILEM F GADINANO ESQ
MCDERMOTT WILL & EMERY
600 13TH STREET N W
WASHINGTON DC 20005

HM12/1010

EXAMINER

BAHAR, M

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/544,984

Applicant(s)

KLEIN ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 19-28 and 37-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 29-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the restriction requirement and remarks submitted July 19, 2001, in Paper No. 7 is acknowledged.

Applicant's election of Group I, claims 1-18 and 29-36 **with traverse** and specie election where R1 is a C5-9 hydroxyalkyl, R2 is methyl, X and Y are NH and Z is C(R3) wherein R3 is an alkylaminoalkyl **without traverse** submitted July 19, 2001, in Paper No. 7 is acknowledged.

Applicant's traversal is based on the argument that the search for Groups I-III together is not an undue burden. Applicant's remarks have been considered but are not persuasive because as shown in the restriction requirement of July 5, 2001, these Groups II and III represent unrelated inventions, and Group I is distinct from Groups II and III because a materially different product can be used to treat inflammatory diseases, see pages 2 and 3 in particular. Given that the diseases encompassed by Groups II and III represent many different fields of medical technology, the search for these vastly different diseases is not co-extensive. Note that the search is not limited to patent files.

Since the elected compound specie recited in claims 8-9 was found to be free of the prior art, the search has been extended to compounds of formula I wherein R1 is a C5-9 hydroxyalkyl, R2 is methyl, X and Y are NH and Z is C(R3) wherein R3 is H or Z is C.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-28 and 37-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in Paper No. 7.

Art Unit: 1617

Claims 1-18 and 29-36 are herein examined on the merits in so far as they read on the elected specie and compounds of formula I wherein R1 is a C5-9 hydroxyalkyl, R2 is methyl, X and Y are NH and Z is C(R3) wherein R3 is H or Z is C.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-7 and 16 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-8 of copending Application No. 09/288556. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

Art Unit: 1617

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-10 of copending Application No. 09/288556. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations recited in the instant claims 17-18 encompass all of the recited limitations of claims 9-10 of copending Application No. 09/288556.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claims 2 and 30 are objected to because of the following informalities: use of parenthetical expression “(mercapto)” is considered informal in claim language. Appropriate correction is required.

Claim 18 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to claims in the alternative only and cannot recite claims “9-

Art Unit: 1617

17". See MPEP § 608.01(n). Accordingly, the claim 18 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 17-18 and 29-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 29 recite the broad recitation "therapeutic compound", and the claim also recites "resolved enantiomers, diastereomers, tautomers, salts and

Art Unit: 1617

solvates” which is the narrower statement of the range/limitation. Also Claim 17 recites “compounds” as the broad range and “compounds of Table 1” as the narrow range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 and 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Novick Jr. (USPN 5,039,666).

Novick Jr. (USPN 5,039,666) teaches compounds and compositions of formulae XII and XVI

tertiary hydroxyalkyls which read on the claimed specie of formula I wherein R1 is a C5-9 hydroxyalkyl, R2 is methyl, X and Y are NH and Z is C(R3) wherein R3 is H or Z is C, see cols. 7 and 8.

Novick Jr. (USPN 5,039,666) does not particularly teach the compounds claimed herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the compounds claimed herein in the compositions of Novick Jr.

One of ordinary skill in the art would have been motivated to employ any of the species of the genus taught in Novick Jr. et al in a pharmaceutical composition because they are members of a genus that is known to be useful in pharmaceutical compositions. One of ordinary skill in the art would reasonably expect similar therapeutic effects from all the species encompassed by the genus.

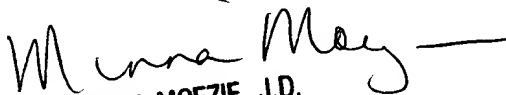
Art Unit: 1617

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
October 5, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600